

JUL 11 2005

K050342

SUMMARY OF SAFETY AND EFFICACY

Theralase™ Inc.

TLC-1000 THERAPEUTIC MEDICAL LASER SYSTEM

April 21st, 2005

I. GENERAL INFORMATION

Device Generic Name: TLC-1000

Trade Name: Theralase TLC-1000 Therapeutic Medical Laser System

Device Classification: Class 2, Performance Standards
21 CFR Part 890.5500 – Infrared Lamp, Non-Heating

Product Code: NHN

Applicant Name and Address: Theralase Inc.
600 Alden Road, Suite 101
Markham, Ontario
L3R 0E7, CANADA
Phone: [1]-905-947-8455
Fax: [1]-905-947-8550

510(k) Number: K050342

II. DEVICE DESCRIPTION

The Theralase™ TLC-1000 Therapeutic Medical Laser System is a non-heating infrared lamp as defined in 21 CFR 890.5500. The TLC-1000 system is a precision medical device consisting of a hand held portable multiple laser probe (5 x 905 NIR laser diodes and 4 x 660 visible red laser diodes) and a laser controller unit with a rechargeable battery.

III. INDICATIONS FOR USE

The Theralase™ TLC-1000 Therapeutic Medical Laser System is indicated for adjunctive use in the temporary relief of pain associated with knee disorders with standard chiropractic practice.

IV. ALTERNATIVE PROCEDURES OR PRACTICES

The primary alternatives for use in treating chronic or acute knee pain include the use of TENS, steroids, non-steroidal anti-inflammatory drugs (NSAIDS) and barbiturated drugs (known to be addictive and relatively toxic).

V. SUMMARY OF CLINICAL STUDIES

The Theralase™ TLC-1000 Therapeutic Medical Laser System was evaluated in a prospective, single blind, randomized controlled study that compared the "Active" Laser with a "Sham" Laser. The multi-center study was conducted at three investigational sites in the United States of America. The study included a total of 122 adult male and female subjects 18 years and older. Enrollment occurred if the following conditions were met: diagnosis of knee pain disorder, moderate to severe symptoms with a pain level of at least 4 as measured by a Pain Level Assessment (VAS) on a scale of 1 – 10, who had failed conservative therapy for at least one month and who had not had previous knee surgery.

Clinical Data Analysis and Results

Statistical analyses were performed by generally accepted statistical techniques to evaluate the differences between the VAS scores from pre-treatment to the 12th treatment and pre-treatment to the 30 day post treatment follow up for patients in Group A (Active Laser) and Group B (Sham Laser).

The statistical analyses of the data demonstrate that the difference between the two treatment groups over time is statistically significant (p-value < 0.05 at the 12th treatment session and p-value < 0.01 at the 30 day post-treatment follow up).

The Theralase™ TLC-1000 Therapeutic Medical Laser System responder rate was 92.4% for subjects in the "Active" Laser group at the end of the laser treatment sessions and 30 day post-treatment follow up compared with 62.5% of the subjects treated with the "Sham" Laser.

No adverse effects from the laser treatments were observed by the principal investigators during the clinical investigational study.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2005

Mr. Roger White
President and CEO
Theralase Incorporated
600 Alden Road, Suite 101
Markham, Ontario L3R OE7 (Canada)

Re: K050342
Trade/Device Name: Theralase™ TLC-1000 Therapeutic Medical Laser System
Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, Non-heating for adjunction use in pain therapy
Regulatory Class: II
Product Code: NHN
Dated: April 28, 2005
Received: April 29, 2005

Dear Mr. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

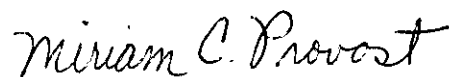
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Roger White

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K050342

Device Name: Theralase™ TLC-1000 Therapeutic Medical Laser System

Indications For Use:

The Theralase™ TLC-1000 Therapeutic Medical Laser System is indicated for adjunctive use in the temporary relief of pain associated with knee disorders with standard chiropractic practice.

Prescription Use: X
(Per 21CFR 801 Subpart D)

AND/OR

Over the Counter Use: _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K050342